DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 9, 2015

Spinal Simplicity, LLC
% Ms. Janice M. Hogan
Hogan Lovells US, LLP
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Re: K140046
Trade/Device Name: Spinous Process Fusion (SPF) Plate
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: PEK
Dated: December 29, 2014
Received: December 29, 2014

Dear Ms. Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K140046

Device Name

Spinous Process Fusion (SPF) Plate

Indications for Use *(Describe)*

The Spinal Simplicity Spinous Process Fusion (SPF) Plate is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions:

- degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radio-graphic studies);
- spondylolisthesis;
- trauma (i.e., fracture or dislocation); and/or
- tumor.

The SPF-Plate is intended for use with bone graft material and is not intended for stand-alone use. The device may be implanted via an open (T1-S1) or percutaneous (L1-S1) approach.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Spinal Simplicity's Spinous Process Fusion (SPF) Plate

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Spinal Simplicity LLC
10995 Quivira Road
Overland Park, KS 66210
Phone: (913) 451 4414
Facsimile: (913) 888 0075
Contact Person: Julie McKee, J.D.
Date Prepared: December 29, 2014

Name of Device

Spinous Process Fusion (SPF) Plate

Common / Classification Name

21 CFR 888.3050
Spinal interlaminal fixation orthosis
Class II
Product code: PEK

Predicate and Reference Devices

Lanx Spinal Fixation System (Aspen) (K071877 – primary predicate)
Globus SP-Fix Spinous Process Fixation Plate (K102195)
X-Spine Axle Interspinous Fusion System (K130438)
Aurora Spine Zip (K133091)
NuVasive Affix Next Gen Spinous Process Plate System (K133052)
NuVasive Affix II Spinous Process Plate System (K132411)
Alphatec Bridgepoint (K103205)
Stryker Universe Plate (K132968)

Intended Use / Indications for Use

The Spinal Simplicity Spinous Process Fusion (SPF) Plate is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions:

- degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radio-graphic studies);
- spondylolisthesis;
- trauma (i.e., fracture or dislocation); and/or
- tumor.

The SPF-Plate is intended for use with bone graft material and is not intended for stand-alone use. The device may be implanted via an open (T1-S1) or percutaneous (L1-S1) approach.

Device Description

The Spinal Simplicity Spinous Process Fusion (SPF) Plate is a minimally invasive, spinous process fusion plate designed for attachment to the posterior, non-cervical spine at the spinous processes through its bilateral locking Plates, and it is intended for use with bone graft fusion material placed within the device. The Spinal Simplicity Spinous Process Fusion (SPF) Plate consists of a Body/Post, Plates, and Fasteners that together form a construct to provide supplemental fusion and stabilization of spinal segments. The components are available in a range of sizes to accommodate varying patient anatomy. Spinal Simplicity Spinous Process Fusion (SPF) Plates are composed of titanium alloys (per ASTM F136 and ASTM F1472).

Technological Characteristics

The SPF-Plate and the predicate devices present very similar technological characteristics, including the device materials, components, and dimensions. The SPF-Plate assembly consists of bilateral Plates and a Body/Post that connects the Plates, similar to the predicate constructs. The SPF-Plate incorporates a deployable feature that allows the Plate to be extended from the implant body after its initial insertion. The device also incorporates a locking hex nut, which is advanced over the Body/Post of the implant, with ratchets that engage with teeth on the Plate. The Plate components of the SPF-Plate and predicate devices similarly include several spikes at the ends of each Plate for attachment to the spinous processes. The SPF- Plate and predicate devices are also available in multiple sizes to accommodate varying patient anatomy. Thus, the technological characteristics of the SPF-Plate compared to the predicate devices are very similar.

Performance Data

Static and dynamic tests of the SPF-Plate have been performed to evaluate the mechanical performance of the device, including the following tests:

- Static Axial Compression Test
- Static Torsion Test
- Dynamic Axial Compression Testing
- Static Axial Pull-Out Test
- Static Plate Dissociation Test
- Cadaver Implantation Studies
- Bone Block Studies to Assess Material Loss and Effect on Mechanical Strength
- Cadaveric Testing to Assess Material Loss and Effect on Mechanical Strength

In all instances, the subject device functioned as intended and the results observed were as expected. Further, performance testing results demonstrated that the SPF-Plate presents substantially equivalent mechanical strength compared to the predicate device.

Spinal Simplicity also collected survey data from surgeons outside the United States who have implanted a version of the subject device. The results of the survey showed that none of the surgeons observed any instances of failure to deploy the device wings, spinous process fracture, or neurological injuries.

Substantial Equivalence

The Spinal Simplicity SPF-Plate has the same intended use and indications for use, and similar technological characteristics and principles of operation as its predicate devices. The technological differences (device dimensions and device design) between the Spinal Simplicity SPF-Plate and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Spinal Simplicity SPF-Plate is substantially equivalent to the predicate devices. Thus, the Spinal Simplicity Spinous Process Fusion (SPF) Plate meets all requirements for a finding of substantial equivalence.

Conclusion

Therefore, the information submitted by Spinal Simplicity in this premarket notification demonstrates that the SPF-Plate performs as intended and is substantially equivalent to the predicate devices.